DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/24/2019-8/2/2019*
	FEI NUMBER 3014362214

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Mr. Bhaskar Krishna, Managing Director/CEO

FIRM NAME	STREET ADDRESS
Global Pharmatech Private Limited	No 32 Sipcot Industrial Complex, Phase I
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hosur, Tamil Nadu, 635126 India	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

On 3/28/2019, the firm received a complaint from their customer, (b) (4), stating that there were tiny particles found in batch #(b) (4) of (b) (4) (b) (4)) Injection (b) (4) ml vial ((b) (4) mg/ml), which is manufactured for the Indian market. The firm received 2 samples for analysis from (b) (4). Tiny floating particles were observed in the vials. Laboratory analysis confirmed that the precipitate peak of the particles matched with (b) (4). The firm's investigation included an assessment of their visual inspection program and concluded that the particles were not present initially and that they were generated over time. However, the investigation did not include an investigation as to how and why these particles were generated over a period of time.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Samina S Khan, Investigator	X	8/2/2019

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SOP #PROD/FR/012, titled, "Entry and Exit Procedure to Aseptic Area", requires use of sterile garments, including goggles, prior to entry into the clean room area. The QA department has not validated the number of cleaning and sterilization cycles through which the goggles can be processed without compromising the integrity of the sterile equipment. Per the manufacturer's recommendation, goggles are limited to 40 sterilization cycles to ensure they maintain integrity. The firm does not have a process in effect to track the number of sterilization cycles the goggles have undergone. These goggles are worn in the Grade B area and are utilized in the manufacturing of (b) (4) Injection ((b) (4) mg/ml) (b) (4) ml, (b) (4) ml, (b) (4) ml vials

***DATES OF INSPECTION**

7/24/2019(Wed), 7/25/2019(Thu), 7/26/2019(Fri), 7/29/2019(Mon), 7/30/2019(Tue), 7/31/2019(Wed), 8/01/2019(Thu), 8/02/2019(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Samina S Khan, Investigator	X	8/2/2019